

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH**

**SUMMARY OF TOXICOLOGY DATA
*AGROBACTERIUM RADIOBACTER***

Chemical Code # 001984, Tolerance # 50136

SB 950 # 245

Original date: January 3, 2002

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, study not submitted
Chronic toxicity, dog:	Data gap, study not submitted
Oncogenicity, rat:	Data gap, study not submitted
Oncogenicity, mouse:	Data gap, study not submitted
Reproduction, rat:	Data gap, study not submitted
Teratology, rat:	Data gap, study not submitted
Teratology, rabbit:	Data gap, study not submitted
Gene mutation:	Data gap, study inadequate, no adverse effect indicated
Chromosome effects:	Data gap, study not submitted
DNA damage:	Data gap, study not submitted
Neurotoxicity:	Not required at this time

Toxicology one-liners are attached.

All record numbers through 117069 were examined.

** indicates an acceptable study.

Bold face indicates a possible adverse effect.

File name: T020103 prepared by J. Gee.

Agrobacterium radiobactor is a biopesticide used on nursery stock to prevent crown gall, caused by a related bacterium, *Agrobacterium tumefaciens*. In June, 1995, US EPA published a Reregistration Eligibility Document, presenting mammalian and human toxicity and exposure potential. At that time, the EPA was requiring no further toxicity testing beyond the acute studies on file. See below.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

No study submitted

CHRONIC TOXICITY, RAT

No study submitted

CHRONIC TOXICITY, DOG

No study submitted

ONCOGENICITY, RAT

No study submitted

ONCOGENICITY, MOUSE

No study submitted

REPRODUCTION, RAT

No study submitted

TERATOLOGY, RAT

No study submitted

TERATOLOGY, RABBIT

No study submitted

GENE MUTATION

008 045325 Moore, L. W., K. Tindall, G. Warren and M. Staver. "Investigation of *Agrobacterium radiobacter* Strain K84 and an Antibiotic it Produces (Agrocin 84) for Mutagenic Activity". (Oregon State U and Montana State U., 1979) *Agrobacterium radiobacter* and the antibiotic it produces were tested for mutagenicity using *Salmonella typhimurium* tester strains TA 1535, TA98 and TA 100, with and without rat-liver activation. The test material was applied as a "spot" on the plates (duplicate plates, three methods). The agrocin migrated through the agar. Results were scored as "++" or "-", rather than by colony count. Positive controls were reported as "++". No evidence of mutagenicity with *A. radiobacter* or agrocin. UNACCEPTABLE (Insufficient information), not upgradeable. (Kishiyama and Gee, 1/2/2002).

CHROMOSOME EFFECTS

No study submitted

DNA DAMAGE

No study submitted

MISCELLANEOUS

Acute:

011 117069 Baltezore, M. "Rabbit Eye Irritation". (Unilab Research, Laboratory Number 9861 and 10056, May 25, 1975.) One-tenth of a ml of Galltrol - A [*A. radiobacter* culture, not described] was applied to one eye of each of the 6 New Zealand rabbits. Eye effects of the cornea in unwashed eyes was prolonged to 21 days for 1 rabbit, grade 1; therefore, a repeat study was performed on 4 rabbits. Eye irritation of the cornea was grade 1 in 1/4 at 24 hours but not present at 48 hours post treatment in the repeat study. Washed eyes of 3 rabbits showed grade 1 corneal affects at 24 hours only.

Category III. UNACCEPTABLE, upgradeable with description of the test article. (Kishiyama and Gee, 1/2/02).

011 117069 Baltezore, M. "Rabbit Skin Irritation". (Unilab Research, Laboratory Number 9861, May 25, 1975.) 0.5 gram of Galltrol - A [*A. radiobacter* culture] was applied once dermally for a 24 hour period to intact and abraded skin to determine the extent of skin irritation using 6 albino rabbits. The material was applied under gauze but no mention was made about moistening. The severity of erythema and edema was slight and not persistent for 7 days. The test article, therefore, was considered not a skin irritant. Category IV. UNACCEPTABLE (Kishiyama and Gee, 1/2/02).

011 117029 Phillips, D. "Acute Oral Infectivity Test" (Northview Pacific Laboratory, Number X2K011, January 17, 1983.) Galltrol A (*Agrobacterium radiobacter* [Strain 84] 1.2×10^8 /ml) at a dose of 5g/kg live cells (20 ml/kg) or killed cells (control) was administered once orally to 5 or 2 Sprague-Dawley rats/sex, respectively. All rats showed signs of pulmonary edema, including those exposed to killed organisms. The study director stated this condition was "not unusual" for this population of animals, obtained from a "reliable" source. No other abnormalities reported in animals observed for 14 days. No deaths occurred. Clearance was not measured. Category IV. ACCEPTABLE . (Kishiyama and Gee, 1/3/02).